Remarks

Claims 1-5 are pending in the subject application. By this Amendment, applicants have amended claim 1. Applicants maintain that the amendment to claim 1 raises no issue of new matter and is fully supported by the specification as filed. Support for the amendment to claim 1 may be found, *inter alia*, in the specification, as originally filed, on page 4, lines 12-17 and lines 22-23. Accordingly, applicants respectfully request entry of this Amendment. Upon entry of this Amendment, claims 1-5 will be pending and under examination.

Rejection Under 35 U.S.C. §112, First Paragraph

In the June 3, 2005 Final Office Action, the Examiner rejected claims 1-5 as allegedly failing to comply with the written description requirement.

In response, applicants respectfully traverse the Examiner's rejection. However, in order to expedite prosecution, but without conceding the correctness of the Examiner's position, applicants have hereinabove amended claim 1. As amended, claim 1 recites that the formulation comprises "*about* 0.03% to *about* 3% by weight tamsulosin" (emphasis added). As the Examiner points out on page 2 of the June 3, 2005 Final Office Action, support for the amendments may be found in the specification at page 4, lines 22-23. Accordingly, applicants maintain that the subject matter of amended claim 1 is described in the specification and respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Rejections under 35 U.S.C. §103(a)

The Examiner rejected claims 1-5 under 35 U.S.C. §103(a) as allegedly unpatentable over Vaghefi et al. (US2003/0157326 A1) in view of Platteeuw (US2005/0106253 A1).

In response, applicants respectfully traverse the Examiner's rejection. However, in order to expedite prosecution, but without conceding the correctness of the Examiner's position, applicants have hereinabove amended claim 1. As amended, claim 1 recites that the formulation is ''a uniform mixture''. Applicants note that neither Vaghefi et al. nor Platteeuw teach such a formulation.

The present invention relates to a sustained release tamsulosin formulation having about 0.03% to about 3% by weight tamsulosin or a pharmaceutical acceptable salt, a hydrophobic polymer, a microsphere forming agent and a diluent. The above components are mixed with knead solution to obtain a uniform mixture. This is done by placing the mixture into an extruding granulator, producing columns which are cut and form a microsphere, so that all components, including the active ingredient, are uniformly mixed.

Vaghefi et al. disclose a sustained release microsphere having an active agent, water insoluble matrix material, disintegrating agent and lubricant. Vaghefi et al. teach a microsphere comprising (a) an interior region comprising a plurality of microcapsules consisting essentially of a core of bioactive compound, and (b) a surface region substantially free of said bioactive compound.
The structures of the sustained release tamsulosin formulation of the instant invention and that of Vaghefi et al. are not the same. The active ingredient of the invention is uniformly distributed in the formulation for more effective sustained

release (See page 2, lines 19-21 and Figure 2 of the subject application).

In contrast, the active ingredient of Vaghefi et al. is present only in an interior region of the microsphere. Moreover, the formulation of the subject invention and that of Vaghefi et al. provide different sustained release, as shown in Fig. 6 of Valghefi et al. and Fig. 1 in the instant application. Similarly, the structure of the pharmaceutical composition of Platteeuw has a granular core containing the active ingredient and an outer layer coated on the granular core.

Applicants maintain that in light of the prior art formulations, the uniformly mixed formulation of the instant invention was not obvious to one skilled in the art. The prior art teaches a coated formulation wherein the active ingredient is stored in an inner compartment and thus has a delayed release after ingestion. The present invention teaches away from this concept as the active ingredient of the subject formulation is uniformly mixed and is therefore present throughout the formulation providing more effective sustained release of the active ingredient.

The Examiner also rejected claims 1-5 under 35 U.S.C. §103(a) as allegedly unpatentable over Fukui et al. (US 4,772,475).

In response, applicants respectfully traverse the Examiner's rejection. However, in order to expedite prosecution, but without conceding the correctness of the Examiner's position, applicants have hereinabove amended claim 1. As amended, claim 1 recites that the formulation is ''a uniform mixture''. Applicants note that Fukui et al. does not teach such a formulation.

In addition, and as the Examiner concedes on page 4 of the June 3, 2005 Final Office Action, Fukui et al. do not teach the claimed amounts of the carrier ingredients of the present invention. The concentrations of the ingredients are critical to the manufacture of the formulation of the invention. For example, a lower concentration of release controlling agent is used to overcome the glue-like problem caused by acrylic acid polymers under high temperature. As stated in the Declaration Under 37 C.F.R. §1.132 submitted as Exhibit B to the March 1, 2005 Amendment filed in connection with this application, this lower concentration provides a solution to the problems of uneven mixtures resulting from the glue-like properties of the mixture containing high concentrations of acrylic polymers. Applicants maintain that Fukui et al. neither teach nor suggest the lower concentration as described in the present application and set forth in the claims presented. The lower concentration of release controlling agent is enabled by applicants' unique uniform mixture. Hence, the lower concentration of release controlling agent as required in the instant invention would not have been obvious to a person of ordinary skill in the art.

In light of the above remarks, applicants maintain that amended claim 1, and claims 2-5 are not rendered obvious by either the combination of Vaghefi et al. and Platteeuw, or by Fukui et al. Accordingly, applicants request that the Examiner withdraw these grounds of rejection.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Missing Parts, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

William E. Pelton Date
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